

## REMARKS

Reconsideration of the above-identified application in view of the amendment above and the remarks below is respectfully requested.

Claim 8 has been canceled in this paper. Claims 1-7, 9, 14 and 20 have been amended in this paper. New claims 22-27 have been added in this paper. Therefore, claims 1-7 and 9-27 are pending and under active consideration.

Claims 1-5 and 8 stand rejected under 35 U.S.C. 102(b) "as being anticipated by Sander et al. (5,522,817)." In support of the rejection, the Patent Office states the following:

Sander et al. disclose, at least in figure 2 and in col. 2, line 65 to col. 3, line 64 and col. 4, lines 32-45; a biocompatible fastener includes a first portion or member and a second portion or member, where the first portion or member (203) is made out of a first bioabsorbable material, and the second portion or member (201) is made out of a non-bioabsorbable material, where the first portion is coated over a portion of the second portion (at the interface between 202 and 204), where the first portion is degradable and can result in fragmentation of the fastener; where the fastener comprises a male member (203) with a post and a head (at 204), and the female member (201) includes bore and a flange extending into the bore (at 202).

Insofar as the subject rejection pertains to claim 8, the rejection is moot in view of Applicants' cancellation herein of claim 8. Insofar as the subject rejection pertains to claims 1-5, Applicants respectfully traverse the subject rejection.

Claim 1, from which claims 2-5 depend, has been amended herein and now recites "[a] biocompatible fastener, said biocompatible fastener comprising a pair of members matingly engageable with one another, at least one of said members comprising an outer coating coated over an inner core, said outer coating comprising a first bioabsorbable material, said inner core comprising one of a second bioabsorbable material and a non-bioabsorbable material, said first

bioabsorbable material having a first degradation rate, said second bioabsorbable material having a second degradation rate, said second degradation rate being slower than said first degradation rate, wherein, after said pair of members have been matingly engaged with one another, degradation of said outer coating over said inner core causes said pair of members to disengage from one another."

Claim 1 is neither anticipated by nor rendered obvious over Sander et al. for at least the reason that Sander et al. does not teach or suggest a biocompatible fastener that, amongst other things, comprises a pair of matingly engageable members wherein at least one said member comprises an outer coating coated over an inner core, the outer coating comprising a first bioabsorbable material, the inner core comprising one of a second bioabsorbable material and a non-bioabsorbable material, the second bioabsorbable material having a degradation rate slower than that of the first bioabsorbable material. Instead, Sander et al. discloses, in Fig. 2, a fastener 200 that comprises a shaft 203 made of a bioabsorbable material and a trocar tip 201 made, for example, from metals or ceramic materials. Although Sander et al. states, at col. 3, lines 5-10, that the bioabsorbable material may contain reinforcing fibers, Sander et al. does not teach or suggest providing an outer coating of a bioabsorbable material over an inner core of a less bioabsorbable material or a non-bioabsorbable material.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 1 and 5-7 stand rejected under 35 U.S.C. 102(b) "as being anticipated by Vandewalle (6,022,352)." In support of the rejection, the Patent Office states the following:

Vandewalle discloses, at least in figures 2, 3, and 8 and in col. 3, line 27 to col. 4, line 8; a biocompatible fastener includes a first portion or sleeve and a second portion or inner core, where the first portion (46) or outer coating is made out of a first bioabsorbable material, and the second portion (50) or inner core is made out of a non-bioabsorbable material, where the fastener comprises male and

female members, where the male member (50) includes a post (54) and a head (56), and the female member (46) defines a bore and a flange (an internal thread) extending into the bore.

Applicants respectfully traverse the subject rejection. Claim 1, from which claims 5-7 depend, is neither anticipated by nor rendered obvious over Vandewalle for at least the reason that Vandewalle does not teach or suggest a biocompatible fastener that, amongst other things, comprises a pair of matingly engageable members wherein at least one said members comprises an outer coating coated over an inner core, the outer coating comprising a first bioabsorbable material, the inner core comprising one of a second bioabsorbable material and a non-bioabsorbable material, the second bioabsorbable material having a degradation rate slower than that of the first bioabsorbable material. Instead, Vandewalle discloses, in Fig. 2, a fastener that comprises a lag screw first part 46 made entirely of a bioabsorbable material and a second part 50 that is made entirely from a non-bioabsorbable material.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 14-19 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Luscombe et al. (5,258,012) in view of Jarrett et al. (5,080,665)." In support of the rejection, the Patent Office states the following:

Luscombe et al. disclose, at least in the figures and in col. 7, lines 18-35, a biocompatible fastener (50) including a male portion (52) with a first base member (54) and first and second male members (56), each including a post and a head (58) with a generally conical, sharp tip; and a female portion (80) comprising a second base member (82) and first and second sleeves (84), each sleeve defining a bore (86) and a flange (90) extending into the bore; where the first and second base members are each generally flat and oval (see figs. 4 and 12), where the first sleeve includes a pair of longitudinal slots (between elements 90 in each bore), where the flange is made of a first bioabsorbable material, and the first base member comprises a second bioabsorbable material. However,

Luscombe et al. do not disclose that the second bioabsorbable material has a degradation rate slower than the degradation rate of the flange. Jarrett et al. teach, at least in col. 7 lines 1-22, that the choice of bioabsorbable materials (and hence, their degradation rates) depends on the desired physical properties of the surgical devices. Thus, it would have been a matter of obvious design choice to apply a second bioabsorbable material that has a degradation rate slower than the degradation rate of the flange in the device of Luscombe et al. The choice would be dependent upon the desired stiffness, as well as the degradation rates, of the components of the fastener.

Applicants respectfully traverse the subject rejection. Claim 14, from which claims 15-19 and 21 depend, has been amended herein and now recites “[a] biocompatible fastener comprising:

(a) a male portion, said male portion comprising

(i) a first base member, said first base member having a bottom surface, and

(ii) a first male member mounted on said bottom surface of said first base member, said first male member comprising a post extending downwardly from said bottom surface, said post having a bottom end, and a head disposed at said bottom end of said post; and

(b) a female portion, said female portion comprising

(i) a second base member, said second base member having a top surface, and

(ii) a first sleeve mounted on said top surface of said second base member and extending upwardly therefrom, said first sleeve defining a bore adapted to receive said head and having at least one flange formed thereon, said at least one flange extending into said bore, said at least one flange being engageable with said head once said head has been inserted therewith so as to inhibit withdrawal of said head from said bore;

(c) wherein at least one of said at least one flange and said head comprises an outer coating coated over an inner core, said outer coating comprising a first bioabsorbable material, said inner core comprising one of a non-bioabsorbable material and a second bioabsorbable material, said

first bioabsorbable material having a first degradation rate, said second bioabsorbable material having a second degradation rate, said second degradation rate being slower than said first degradation rate; and

(d) wherein degradation of said first bioabsorbable material facilitates withdrawal of said head past said at least one flange.”

Claim 14 is patentable over Luscombe et al., in view of Jarrett et al., for at least the reason that Luscombe et al. and Jarrett et al., whether taken individually or in combination, do not teach or suggest a biocompatible fastener comprising, amongst other things, a male member comprising a post and a head and a female member comprising a sleeve with a bore and at least one flange, wherein at least one of said at least one flange and said head comprises an outer coating comprising a first bioabsorbable material coated over an inner core comprising one of a non-bioabsorbable material and a second bioabsorbable material, said first bioabsorbable material having a degradation rate that is faster than said second bioabsorbable material or said non-bioabsorbable material.

Instead, Luscombe et al. discloses a fastener 50 that comprises a staple 52 and a receiver 80. Luscombe et al. teaches that “the receiver 80 can be made of a bioabsorbable polymer or plastic material such as polydioxanone...and the staple 52 can be made of a blend of lactide/glycolide copolymer and polyglycolic acid (PGA).” However, Luscombe et al. does not teach or suggest that its head and/or its flange comprises an outer coating comprising a first bioabsorbable material coated over an inner core comprising a non-bioabsorbable material or a second bioabsorbable material, the second bioabsorbable material having a slower degradation rate than the first bioabsorbable material. This deficiency of Luscombe et al. is not cured by Jarrett et al., which merely discloses various blends of bioabsorbable materials.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 9-13 have been allowed; however, in view of the fact that claims 9-13 are identical to claims 5-9, respectively, of U.S. Patent No. 6,692,507 (U.S. Patent No. 6,692,507 having issued from USSN 09/935,950 - the parent application to the present application), Applicants are herein amending claim 9 to additionally specify that the recited flange is substantial circumferential. Support for this amendment may be found in the present specification, for example, at page 11, line 10.

Claim 20 stands objected to "as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims."

Applicants have rewritten claim 20 in independent form. Accordingly, the subject objection has been overcome and should be withdrawn.

New claims 22-27 depend indirectly from claim 1 and are patentable for at least the same reasons as claim 1.

It is respectfully submitted that the present application is in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is

required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: November 30, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 30, 2006

  
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Dated: November 30, 2006